

# **PMA P010018/S5**

## **QUESTIONS FOR PANEL DISCUSSION**

- ?? Is the length follow-up sufficient to demonstrate reasonable assurance of safety and efficacy for the requested indication?
- ?? Is the magnitude of induced cylinder and axis shift, and the associated effect on UCVA, clinically acceptable for the requested indication?
- ?? Is the rate of undercorrection >1D clinically acceptable?  
Are there subgroups of the PMA cohort for which this outcome is not acceptable?
- ?? Are the reduced accuracy to target refraction and poorer near-UCVA outcomes (monocular and binocular) reasonable to justify the risk of elective surgery with “temporary” results, and is the near UCVA correction achieved clinically useful in the following groups? If not, how do you suggest the indication and/or labeling be modified...
  - ?? for eyes treated with the 32-spot pattern?
  - ?? for subjects >55 years of age?
  - ?? for hyperopic patients?
  - ?? for any other subgroups or attempted magnitude of refractive correction?
- ?? Do the spectacle dependence rates for near activities support approval for the requested indication in a presbyopic population?
- ?? Do the safety and efficacy data support approval for the requested indication?  
If not, what indication does the data support?
- ?? Do you have additional labeling recommendations, explanatory text or data?  
Are there data tables that should be added to the labeling for physicians and/or patients?